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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
| 10/580,922 | 03/15/2007 | Barry Slobedman | SPRUS61.001APC | 8791 |
| 20995 7590 06/08/2010 KNOBBE MARTENS OLSON & BEAR LLP 2040 MAIN STREET FOURTEENTH FLOOR IRVINE, CA 92614 | | | EXAMINER STOICA, ELLY GERALD | |
| | | | ART UNIT 1647 | PAPER NUMBER |
| | | | NOTIFICATION DATE 06/08/2010 | DELIVERY MODE ELECTRONIC |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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|------------------------------|---------------------------------------|---|--|
| Office Action Summary | Application No. 10/580,922 | Applicant(s) SLOBEDMAN ET AL. | |
| | Examiner ELLY-GERALD STOICA | Art Unit 1647 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 March 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,6-8,24,28,30-32,40-44,52 and 58 is/are pending in the application.
- 4a) Of the above claim(s) 31,32 and 40-44 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,6-8,24,28,30,52 and 58 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 30 May 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date <u>02/11/2008</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election of Group I (claims 1-2, 6-8, 24, 28,30, 31-32, 52 and the new claim 58) and of the specie SEQ ID NO: 1 in the reply filed on 03/26/2010 is acknowledged. Because applicant did not distinctly and specifically point out any errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Claims 2-5, 9-23, 25-27, 29, 33-39, 45-51 and 53-57 were canceled by Applicant. Claims 1, 6-8, 24, 28, 30-32, 40-44, 52 and 58 are pending. Claims 31-32 and 40-44 are withdrawn for being drawn to non-elected subject matter. Claims 1, 6-8, 24, 28, 30, 52 and 58 are currently examined.

Information Disclosure Statement

2. The information disclosure statement (IDS) submitted on 02/11/2008 is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 1, 6-8, 24, 28, 30, 52 and 58 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims

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contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

The base claim 1 contains the recitation “comprising at least 19 consecutive nucleotides”. This limitation was not present in the Specification at the time of filing. The other claims were rejected as dependent claims.

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claim 52 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: decision of diagnosis directly linked to the presence of the hybridization.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 1, 24, 28, 3052 and 58 are rejected under 35 U.S.C. 102(b) as being anticipated by Pestka et al. (WO/2001/016153, published 03/08/2001- cited by Applicant).

Pestka et al. teach a new viral interleukin 10, homologous to cellular IL-10, and encoded by the UL 111a open reading frame of the CMV genome. The sequence identity of the SEQ ID NO: 1 of the instant Application and the polynucleotide sequence of Pestka et al. is featured below:

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Qy  28 CAGTTGGGCGGCGGACTGGGACGGCATGCTGCGGTGATGCTGTCGGTGATGGTCTCTTCC 87
      |||
Db   1 CAGTTGGGCGGCGGACTGGGACGGCATGCTGCGGCGATGCTGTCGGTGATGGTCTCTTCC 60

Qy  88 TCTCTGGTCCTGATCGTCTTTTTTCTAGGCGCTTCCGAGGAGGCGAAGCCGGCGACGACG 147
      |||
Db  61 TCTCTGGTCCTGATCGTCTTTTTTCTAGGCGCTTCCGAGGAGGCGAAGCCGG---CGACG 117

Qy 148 ACGACGATAAAGAATACAAAGCCGCAGTGTCTGTCAGAGGATTACGCGACCAGATTGCAA 207
      |||
Db 118 ACGACGATAAAGAATACAAAGCCGCAGTGTCTGTCAGAGGATTACGCGACCAGATTGCAA 177

Qy 208 GATCTCCGCGTCACCTTTCATCGAGTAAAACCTACGTT----- 245
      |||
Db 178 GATCTCCGCGTCACCTTTCATCGAGTAAAACCTACGTTGGTAGGTCACGTAGGTACGGTT 237

Qy 246 -----GCAACG 251
      |||
Db 238 TATTGCGACGGTCTTTCTTTTCCGCGTGTCGGGTGACGTAGTTTTCTCTTGTAGCAACG 297

Qy 252 TGAGGACGACTACTCCGTGTGGCTCGACGGTACGGTGGTCAAAGGCTGTTGGGGATGCAG 311
      |||
Db 298 TGAGGACGACTACTCCGTGTGGCTCGACGGTACGGTGGTCAAAGGCTGTTGGGGATGCAG 357

Qy 312 CGTCATGGACTGGTTGTTGAGGCGGTATCTGGAGATCGTGTTCCCGCAGGCGACCACGT 371
      |||
Db 358 CGTCATGGACTGGTTGTTGAGGCGGTATCTGGAGATCGTGTTCCCGCAGGCGACCACGT 417

Qy 372 CTATCCCGGACTCAAGACGGAATTGCATAGTATGCGCTCGACGCTAGAATCCATCTACAA 431
      |||
Db 418 CTATCCCGGACTCAAGACGGAATTGCATAGTATGCGCTCGACGCTAGAATCCATCTACAA 477

Qy 432 AGACATGCGGCAATGCGTAAGTGTCTCTGTGGCGGCGCTGTCCGCACAGAGGTAACAACG 491
      |||
Db 478 AGACATGCGGCAATGTGTAAGTGTCTCTGTGGCGGCGCTGTCCGCACAGAGGTAACAACG 537

Qy 492 TGTTTCATAGCACGCTGTTTTACTTTTGTCTGGGCTCCCAGCCTCTGTTAGGTTGCGGAGAT 551
      |||
Db 538 TGTTTCATAGCACGCTGTTTTACTTTTGTCTGGGCTCCCAGCCTCTGTTAGGTTGCGGAGAT 597

Qy 552 AAGTCCGTGATTAGTCGGCTGTCTCAGGAGGCGGAAAGGAAATCGGATAACGGCACGCGG 611
      |||
Db 598 AAGTCCGTGATTAGTCGGCTGTCTCAGGAGGCGGAAAGGAAATCGGATAACGGCACGCGG 657
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Qy 612 AAAGGTCTCAGCGAGTTGGACACGTTGTTTAGCCGTCTCGAAGAGTATCTGCACTCGAGA 671
      |||
Db 658 AAAGGTCTCAGCGAGTTGGACACGTTGTTTAGCCGTCTCGAAGAGTATCTGCACTCGAGA 717

Qy 672 AAGTAGCGTTGCGATTTGCAGTCCGCTCCGGTGTCTCGTTCACCCAGTTACTTTAATAAACG 731
      |||
Db 718 AAGTAGCGTTGCGATTTGCAGTCCGCTCCGGTGTCTCGTTCACCCAGTTACTTTAATAAACG 777

Qy 732 TACTGTTTAACC 743
      |||
Db 778 TACTGTTTAACC 789

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As can easily be seen from the alignment , there is a plethora of sequences comprising at least 19 consecutive nucleotides of SEQ ID NO:1 of the instant Application (the Qy- line) which are identical with the SEQ ID NO: 1 (*cmvIL-10*) of the Pestka et al. reference. In addition, Pestka et al. teach kits that contain fragments of the nucleic acid of their Invention and reagents for detection of the nucleic acid of *cmvIL-10* (p. 7, lines 7-19; claim 13). Also described are methods for detecting a CMV infection from serum or tissue samples from patients, based on the detection of *cmvIL-10* by hybridization with fragments of SEQ ID NO:1 (page 6, lines 5-25; claim 12).

Since the claims 1, 24, 28, 30, 52 and 58 are drawn to any fragment that contains at least 19 consecutive nucleotides from SEQ ID NO: 1 which is identical with extensive tracts of the Pestka et al. sequence, the claims are anticipated by Pestka et al.

Conclusion

9. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ELLY-GERALD STOICA whose telephone number is

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(571)272-9941. The examiner can normally be reached on 9:00-18:30 M-Th and 9:00-18:30 alternate F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary B. Nickol can be reached on (571) 272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Elly-Gerald Stoica/
Examiner, Art Unit 1647